5. 510(k) Summary (21 CFR 807.92)

FEB 19 2013

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K120851

Submitter's name:	Christopher Relyea
Submitter's address:	160 West 71st Street, 18th Floor, New York, NY 10023, USA
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Name of contact person:	Christopher Relyea
Date the summary was prepared:	10/18/2012

Device Name/Trade Name:	Communify PACS Viewer 1.5
Common Name:	Medical Image Workstation
Classification Name:	21 CFR 892.2050
Product Code	LLZ

Substantially equivalent to the devices are the following:

Manufacturer	Device	510(k)
Flying Squirrel Storage	Communify PACS Viewer 1.0	K110797
MIM Software Inc. (formerly MIMvista Corp.)	MIMviewer 4.1	K071964

Comparison to Predicate Devices

Communify PACS Viewer 1.5 is an extension of the Communify PACS Viewer 1.0 that includes all of the 1.0 version's capabilities, such as the ability to process and display medical images from DICOM compliant modalities such as CR, CT, DX, MR, NM, PT, RF, US, XA, and others. MIM is also a PACS viewer. Like MIM, Communify PACS Viewer 1.5 supports the ability to read and visualize DICOM-RT data files, such as Structure Set, Dose, Dose Value Histogram and Plan (Beam) data.

Conclusion

Similar to the predicate devices, the Communify PACS Viewer 1.5 system allows the display and measurement of medical images, but does not alter the source data and original image. All devices require that use is restricted to suitably licensed healthcare professionals. It is our conclusion that Communify PACS Viewer 1.5 is significantly comparable to the Communify PACS Viewer 1.0 and MIM devices.

Device Description

Communify PACS Viewer (version 1.5) is a Picture Archiving and Communications System (PACS) viewer application which allows users to view, manipulate, annotate, transmit to other facilities, print, and animate all manners of DICOM and DICOM-RT images and modalities. These modalities include, but are not limited to, CR, CT, DX, MR, NM, PT, RF, US, and XA.

Communify PACS Viewer 1.5 contains common image manipulation functions (such as zoom, pan, triangulation, and window/level) and common image labeling tools (including measurements tools, drawing tools, and annotation overlays). The annotation overlay displays all the important metadata (as configured by the user) for each displayed series study. Although annotation fields depend on the modality and the patient study, the Annotation Overlay Template Wizard provides a full list of annotation fields the user can assign into the image display. For RT studies, Communify PACS Viewer 1.5 allows the visualization of the RT Structure Set, Dose, Dose Value Histogram, and Plan data.

There are shortcut keys, toolbars, and right-click menus for easy access to tools and features. The Hanging Protocol editor of the Communify PACS Viewer configures the presentation layout of images on the screen when a study is loaded. This allows commonly used display formats and presets to be saved and easily accessed to allow for faster case study reviews.

Performance Data

Software verification and validation was performed following FDA guidance for "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Tests were conducted successfully to address issues in the hazard analysis, confirm the functionality in the verification and validation section and to provide comparisons of samples with 510(k)-cleared DICOM-RT readers.

Intended Use Statement

Communify PACS Viewer is a Picture Archiving and Communications System (PACS) viewer designed to be

used to view Digital Imaging and Communications in Media (DICOM), DICOM-RT and non-DICOM information and data. Communify PACS Viewer is a software application that runs on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. Communify PACS Viewer is an image and display software that accepts DICOM data from any OEM modality which supports DICOM standard imaging data; the system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulations, create graphical representations of anatomical areas, and perform quantitative measurements.

Communify PACS Viewer is designed to support the use and viewing of DICOM-RT (radiotherapy extensions), such as Structure Set, Contour, Dose, Dose Value Histogram and Plan information.

In Communify PACS Viewer, mammographic images are viewed in mammography monitors that are cleared or approved by FDA. Users should not apply lossy compression to mammographic images and only DICOM "for presentation" mammography images may be displayed. Communify PACS Viewer does not manipulate or edit any mammography image acquisition system manufacturer's proprietary image processing methods.

Please note that Communify PACS Viewer does not run on mobile smartphones and tablets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 19, 2013

Communify Health
c/o Chris Relyea
160W 71ST
18 Floor
New York, NY 10023

Re: K120851
Trade/Device Name: Communify PACS Viewer (version 1.5)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 30, 2012
Received: February 12, 2013

Dear Mr. Relyea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120851 .

Device Name: Communify PACS Viewer (version 1.5)

Indications for Use:

The Communify PACS Viewer 1.5 is a Picture Archiving and Communications System (PACS) viewer designed to be used to view Digital Imaging and Communications in Media (DICOM), DICOM-RT and non-DICOM information and data. The Communify PACS Viewer 1.5 is a software application that runs on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems. Communify PACS Viewer is an image and display software that accepts DICOM data from any OEM modality which supports DICOM standard imaging data; the system provides the capability to organize images generated by OEM vendor equipment, perform digital manipulations, create graphical representations of anatomical areas, and perform quantitative measurements.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k)_____K120851_____